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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,012	09/01/2000	Karen A. Kreutz	8241	5529

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EXAMINER

KIDWELL, MICHELE M

ART UNIT PAPER NUMBER

3761

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/653,012

Applicant(s)

KREUTZ ET AL.

Examiner

Michele Kidwell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 – 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moder (US 5,986,165).

With reference to claim 1, Moder et al. (hereinafter "Moder") discloses a feminine hygiene kit comprising an absorbent tampon (14), said tampon comprising an absorbent core and a withdrawal mechanism attached thereto (col. 9, line 54 to col. 10, line 24 and figure 4) and a backup feminine protection product (12) wherein the tampon and the backup feminine protection product are packaged in a common package as set forth in col. 6, lines 47 – 55.

The difference between Moder and claim 1 is the provision that the absorbent core has a synergistic absorbent capacity of less than 6 grams.

It would have been obvious to one of ordinary skill in the art to modify the kit of Moder by providing an absorbent tampon having an absorbent core with a synergistic absorbent capacity of less than 6 grams because Moder discloses the use of three of the four absorbencies designated by the FDA in his patent and states that depending upon the desired absorbency one desires in the finished tampon, the basis weight of the

absorbent ribbon can vary as set forth in col. 20, lines 1 – 13. Therefore, it would only require ordinary skill in the art to provide a lighter absorbency, i.e. the use of a junior tampon – the forth absorbency designated by the FDA, if desired. Likewise, since Moder discloses a “regular” absorbency, a “super” absorbency and a “super-plus” absorbency, it shows that Moder recognizes the advantages of making different absorbencies available in the kit for use based on the desire of the consumer. Therefore, it would have been obvious to include a “junior” absorbency, if desired, in the same type of kit disclosed by Moder.

Regarding claim 2, Moder discloses a feminine hygiene kit wherein the backup feminine protection product is a pantiliner as set forth in col. 6, lines 24 – 26.

As to claim 3, Moder discloses a feminine hygiene kit wherein the pantiliner has a caliper of less than or equal to about 3 mm as set forth in col. 7, lines 40 – 41.

With reference to claim 4, Moder discloses a feminine hygiene kit wherein the backup feminine protection produce is a sanitary napkin as set forth in col. 8, lines 44 – 48.

With respect to claim 5, Moder discloses a feminine hygiene kit wherein the backup feminine protection product is an absorbent interlabial device as set forth in col. 3, lines 5 – 9.

Claims 1, 6 and 8 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stravitz (US 6,164,442).

With reference to claim 1, Stravitz discloses a feminine hygiene kit comprising an absorbent tampon and a backup feminine protection product wherein the tampon and

the backup feminine protection product are packaged in a common package as set forth in col. 6, lines 8 – 38.

The difference between Stravitz and claim 1 is the provision that tampon have a withdrawal mechanism attached thereto and that the absorbent core have a synergistic absorbent capacity of less than 6 grams.

Stravitz does not explicitly state that the tampon provided in the kit has a withdrawal mechanism attached thereto. However, it is well known in the art that the basic structure of a tampon includes a withdrawal mechanism attached thereto. Additionally, Moder provides a tampon with a withdrawal mechanism attached thereto.

It would have been obvious to one of ordinary skill in the art to modify the tampon of Stravitz by providing a withdrawal mechanism because the withdrawal string will provide a safe and reliable means by which the tampon can be withdrawn from a woman's vagina after it has absorbed a certain amount of menstrual fluid as taught by Moder in col. 19, lines 34 – 39.

Moder also provides an absorbent tampon having an absorbent core with a synergistic absorbent capacity of from 6 grams to over 12 grams.

It would have been obvious to one of ordinary skill in the art to modify the tampon of Stravitz to provide a tampon with a synergistic absorbent capacity of less than grams because Moder discloses the use of three of the four absorbencies designated by the FDA in his patent and states that depending upon the desired absorbency one desires in the finished tampon, the basis weight of the absorbent ribbon can vary as set forth in col. 20, lines 1 – 13. Therefore, it would only require ordinary skill in the art to provide a

absorbency, i.e. the use of a junior tampon – the forth absorbency designated by JA, if desired. Likewise, since Moder discloses a “regular” absorbency, a “super” absorbency and a “super-plus” absorbency, it shows that Moder recognizes the advantages of making different absorbencies available in the kit for use based on the desire of the consumer.

Further, the applicant states on page 10 of the specification that the use of a tampon having an absorbency in the range of less than or equal to about 6 grams offers several advantages in the learner's kit of the claimed invention. This statement provides support for the reasoning that the regular absorbency tampon will function equally as well as a junior absorbency tampon and that substituting a junior absorbency tampon for a regular absorbency tampon would only require ordinary skill in the art.

Regarding claim 6, Stravitz provides a feminine hygiene kit comprising a tampon a backup feminine protection product and a mirror packaged together in a common package as set forth in col. 6, lines 8 – 32.

With respect to claims 8 and 19 – 20, it is well known in the art to package a tampon with a tampon insertion guide and/or instruction booklet which would thereby assist the user in creating a tampon usage system, in order to provide the user with personal assistance and necessary guidelines associated with using the product.

It would have been obvious to one of ordinary skill in the art to modify the feminine hygiene kit of Stravitz to include such guides and/or instructions to provide assistance to users that are not familiar with tampon usage.

With reference to claims 9 and 14 – 18, it would have been obvious to one of ordinary skill in the art to modify the feminine hygiene kit of Stravitz to employ any and/or all of the claimed limitations based on the targeted population because the purpose of the kit in general is to provide convenience to the user. Likewise, Stravitz discloses that a space is provided in the kit to accommodate additional items or articles as desired as set forth in col. 6, lines 13 – 15.

Claims 10 – 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stravitz, as applied to claims 1 and 6 and further in view of Morrow (US 5,988,386).

The difference between Stravitz and claim 10 is the provision that the feminine hygiene kit further comprises an insertion glove.

Morrow teaches a feminine hygiene kit further comprises a glove as set forth in col. 11, lines 41 – 43.

It would have been obvious to one of ordinary skill in the art to modify the feminine hygiene kit of Stravitz to include a glove because the glove allows the woman's hand to remain sanitary while inserting/removing the tampon as taught by Morrow in col. 11, lines 50 – 52. While the glove of Morrow is explicitly disclosed as a removal glove, the glove remains fully capable of being used as an insertion glove and serves the same purpose as the insertion glove.

Regarding claims 11 – 13, Morrow teaches the claimed limitations as set forth in col. 11, lines 33 – 58.

Response to Arguments

Applicant's arguments filed December 26, 2002 have been fully considered but they are not persuasive.

Initially, the applicant argues that the Office Action does not set forth a proper showing of a suggestion or motivation to make the required modification. The examiner disagrees with this assertion and refers again to col. 20, lines 1 – 13 of the reference. This passage discloses that the basis weight of the absorbent ribbon can vary depending upon the desired absorbency of the finished tampon. Therefore, it would have been obvious to one of ordinary skill in the art to modify the basis weight of the disclosed tampons (i.e., the sizes disclosed as “regular”, “super” and “super-plus”) since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

In reply to the applicant's argument that the FDA recognizes 6 categories of tampon absorbency and not 4, the examiner would like to add that these absorbencies provided by the applicant are recognized as of April 1, 2002. The FDA has not always designated six absorbencies. The “traditional” absorbency terms are “regular”, “super” and “super-plus.” The remaining three absorbencies were added at a later date in order to make the tampon absorbency, that initially varied from brand from brand to brand, correlate throughout the industry.

Previously, the examiner asserted that “the applicant states on page 10 of the specification that the use of a tampon having an absorbency in the range of less than or equal to about 6 grams offers several advantages in the learner's kit of the claimed

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invention. This statement provides support for the reasoning that the regular absorbency tampon will function equally as well as a junior absorbency tampon and that substituting a junior absorbency tampon for a regular absorbency tampon would only require ordinary skill in the art.” The applicant responds by stating that according to the cited “evidence”, that has been revised as of April 2002, teaches the “regular” absorbency to be greater than 6 grams. The examiner maintains her position in that even if the regular absorbency is found to be greater than 6 grams, 6.01 grams is still **about** 6 grams and would still function equally as well as a junior absorbency tampon according to the applicant’s specification.

Furthermore, the applicant relies on the advantages associated with using a tampon having an absorbency of less than 6 grams in a learner’s kit of the claimed invention. The specification states, among other things, that the use of a lower absorbency tampon feels more comfortable, eases removal, etc. It is noteworthy to add that a lower absorbency tampon is not limited to use for teens and vice versa. In fact, the term “junior” absorbency has been changed to “lite” absorbency to avoid such confusion. A lower absorbency tampon is suitable for just that.....a light flow. Just because a consumer may be younger or a novice using the claimed invention does not mean that the consumer will have a light flow. The Moder reference recognizes the combination of a tampon having all of the traditional absorbencies in combination with a backup absorbent article for added protection. For one of ordinary skill in the art to modify the traditional absorbency ranges to include absorbency ranges added by the FDA at a later date, ranges that fall within +/- 1 gram on either end of the ranges already

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disclosed, in combination with the fact that the Moder reference explicitly teaches that the absorbency of the disclosed tampon may be varied depending upon the desired finished product, would be an obvious modification motivated by the reference and the proposals and/or revisions made to the Code of Federal Regulations provided by the FDA.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Kidwell whose telephone number is 703-305-2941. The examiner can normally be reached on Monday - Friday, 7:30am - 4:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Michele Kidwell
March 23, 2003


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